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I also certify that the attached copy of the request for grant of a Patent (Form 1/77) bears a correction, effected by this office, following a request by the applicant and agreed to by the Comptroller-General.

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1. Your reference — WN/MSR/IXA.17

2. Patent application number *(The Patent Office will fill this part in)* — 0401455.1

3. Full name, address and postcode of the or of each applicant *(underline all surnames)*

IXA Medical Products ~~Limited~~ Liability Partnership
54 Bath Road
Cheltenham
Gloucestershire GL53 7HG

PF Fa177 25.1.05

Patents ADP number *(if you know it)* — ~~8793162001~~ 8166530001

If the applicant is a corporate body, give the country/state of its incorporation — United Kingdom

4. Title of the invention — A Defibrillator Device

5. Name of your agent *(if you have one)* — Wynne-Jones Laine & James

"Address for service" in the United Kingdom to which all correspondence should be sent *(including the postcode)*

22 Rodney Road
Cheltenham
Gloucestershire
GL50 1JJ
United Kingdom

Patents ADP number *(if you know it)* — 1792001

6. Priority: Complete this section if you are declaring priority from one or more earlier patent applications, filed in the last 12 months.

Country	Priority application number *(if you know it)*	Date of filing *(day / month / year)*

7. Divisionals, etc: Complete this section only if this application is a divisional application or resulted from an entitlement dispute *(see note f)*

Number of earlier UK application	Date of filing *(day / month / year)*

8. Is a Patents Form 7/77 (Statement of inventorship and of right to grant of a patent) required in support of this request? — Yes

Answer YES if:
a) any applicant named in part 3 is not an inventor, or
b) there is an inventor who is not named as an applicant, or
c) any named applicant is a corporate body.
Otherwise answer NO (See note d)

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Patents Form 1/77

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Continuation sheets of this form	
Description	14 pages
Claim(s)	
Abstract	
Drawing(s)	2 pages

10. If you are also filing any of the following, state how many against each item.

Priority documents	
Translations of priority documents	
Statement of inventorship and right to grant of a patent (Patents Form 7/77)	
Request for a preliminary examination and search (Patents Form 9/77)	
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11. I/We request the grant of a patent on the basis of this application

Signature(s) Wynne-Jones, Laine & James Date 23 January 0

12. Name, daytime telephone number and e-mail address, if any, of person to contact in the United Kingdom William Joseph Newell (01242) 515807

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A DEFIBRILLATOR DEVICE

This invention relates to defibrillators, and in particular, but not exclusively, automatic or semi-automatic external defibrillators (AEDs). Further this invention relates to a defibrillator that is automatically activated or inactivated by, for example, touching or holding a sensory section or sections of the casing.

BACKGROUND

In England only two to three people in every hundred survive Sudden Cardiac Death (SCD) compared with eight to nine in Scotland and eleven in the United States. In the United States, on average, 1000 people per day die; this translates into one death every two minutes

Over 80% of SCD cases are caused by ventricular fibrillation ("VF"), in which the heart's muscle fibres contract without any coordination, resulting in a significantly reduced blood flow to the body. Currently, the most effective and widely used treatment for VF is electrical defibrillation, which applies an electrical shock through the patient's heart, clearing the abnormal electrical activity (a process called "defibrillation") by depolarising a critical mass of myocardial cells to allow spontaneous organized myocardial depolarisation to resume.

To be most effective, the defibrillation shock must be delivered to the patient within minutes of the onset of VF. It is well documented that defibrillation shocks delivered within one minute after the onset of VF achieve up to a 100% survival rate. However, statistically the survival rate falls by approximately 10% per minute and beyond 10 minutes, the survival rate approaches zero.

Importantly, the more time that passes, the longer the brain is deprived of oxygen and the more likely that brain damage will result.

In the course of a rescue, even if the patient is discovered immediately, it can take a few minutes to retrieve the AED and a few additional minutes for the AED to diagnose and treat the patient. As can be appreciated, the less time required for an operator to activate and set up the AED, the better the chances that the patient will survive.

Government policies and growing awareness of AEDs has led to a greater proliferation of easily accessed public devices. This in turn has brought the devices to a wider public audience where an operator has a greater likelihood of having little of no training in the use of an AED. Even where the operator has had training he or she may well be unfamiliar with a particular brand of AED device and this can lead to confusion or even panic at the onset of a rescue trying to determine how to activate the AED.

Traditionally, it is considered universal that the on/off switch may use a "1" to indicate "on", and a "0" to indicate "off." However, the recognition of the on/off switch is often confusing to someone without prior knowledge or experience, particularly when under extreme stress. Furthermore, AEDs generally have had several buttons for performing differing functions such as SHOCK and ANALYSE and the location of an on/off switch can be confusing to find.

An AED is needed, that is capable of walking the operator through the stages of a rescue with the operator performing a minimum of functions in a very simple way and requiring no special knowledge of how to operate the device.

US Patent No. 6556864 describes a defibrillator that is automatically activated or inactivated by, for example, inserting or removing an object, such as a plug or a pin, from a receptacle. It is stated that the object could be related to an electrode, whereby removing the electrode causes the device to turn on. However this system still requires an operator to know that in order to use the device he has to first remove an object such as the electrode. There is a risk that in operation the operator may waste valuable time looking for an obvious "ON" button as he may be familiar with devices having an ON button. This is especially true if the operator is panicking and is not aware of or does not pay attention to any displays instructing him to remove an object first.

US Patent No. 5645571 describes a device in which opening the lid covering the electrode compartment to expose the electrodes causes the AED to be powered ON; Again, this device requires the operator to have the knowledge that he has to first lift a lid to activate the device. Without prior knowledge valuable time could again be wasted.

US Published Application No. 20030120311 describes a device which automatically turns on when an operator removes it from a storage location. In this arrangement an AED is automatically activated without the operator requiring prior knowledge of performing some special act of removing or lifting something connected with the device and so overcomes the limitations of the arrangements described in the above two US patents. However, this arrangement requires that the AED remain in a storage case at all times when not in use and hence adds to the weight and bulkiness of the device when in

transit. Such a situation would be undesirable in many applications, particularly when portability is a key issue, for example where trained operators at a concert event or show carry the device across the shoulders in a carry bag.

SUMMARY OF THE INVENTION

Accordingly, we have designed an improved defibrillator device which changes its operational state when touched or handled on a sensory section or sections of the casing and particularly without requiring the operator to determine the location of an ON/OFF switch to activate it. Thus in particular embodiments of this invention, the defibrillator changes its operational state when touched or handled on a sensory section or sections of the casing.

In one aspect, this invention provides a defibrillator device comprising a casing containing electrical circuitry for generating in use a defibrillation voltage for application to a patient, a control system for controlling operation of said defibrillator device, and a detector means which is associated with at least one region of said casing and which is responsive to at least one of touching or handling by, or proximity of, an operator, said system being responsive in use to said detector means to change the operational status of said defibrillator device from a first state to a second state on detection of an operator.

In this way the operational status of the defibrillator device changes without requiring the operator to identify the whereabouts of the ON/OFF switch and also without requiring any specific action such as the removal of items, opening of a casing or removal from a casing, etc. Thus in preferred embodiments the change in operational status is effected without requiring any specific actions normally associated with turning on the defibrillator.

device to a different operational state which may be the same or different to the first operational state.

The first operational state may be an OFF mode; alternatively it may be a sleep mode. Such a mode is designed to conserve power by deactivating all non-essential components until absolutely needed. In use, this mode may be controlled by a counter and interrupt circuit. When entering the sleep mode all non-essential and non-volatile components are turned off and the counter is activated. Thus at a predetermined time the counter turns on and triggers the interrupt; essential components required to maintain the operating reliability of the device are activated (i.e. the unit "wakes up") to perform a self check. The interrupt may also be triggered by an external factor such as a switch or other form of detector (heat, movement etc.) Such sleep modes are well known in the art and can maintain the unit in a state of readiness, but at less than 0.5% of the operating power.

The second state may be an ON state or, where the control system is operable to effect a self-test routine, the second state may be a self-test organisational state.

The control system may be responsive to the absence of touching, handling or proximity of an operator within a pre-set period to change the operational status of the device to a further state which may be the same or different to the first state. In this arrangement the defibrillator may be returned to an OFF or sleep mode after a pre-determined absence, or the device may change from an ON or self-test operational state to a further operational state prior to delivery of the defibrillation voltage.

Preferably, the defibrillator device includes means for issuing instructions to an operator following detection by said detector means; the instructions may be verbal, issued via a loudspeaker or the like, and/or visual issued by a display on the defibrillator device.

Preferably the control means is operable to issue an instruction to the operator to connect a further item of equipment, such as a pair of electrodes, on detecting absence of an operator following the change from said first operational state to second operational state.

Additionally, or alternatively, the control system may issue an instruction for the operator to touch or trip a further sensor on detecting absence of the operator following said change from said first operational state to said second operational state.

The defibrillator device may include one or more attitude sensors for detecting the attitude of the casing and for supplying the corresponding attitude signals to said control system. This allows the control system to determine the orientation of the defibrillator device, with a certain orientation being associated with the defibrillator device being carried, and another orientation being associated with it being laid on the ground right way up, and so on.

In one arrangement, after application of a defibrillation voltage in use to a patient, detection by said detector means of the presence or absence of operator (or a pre-determined sequence of presence/absence) causes the device to provide and/or store post-rescue data.

In another arrangement, where the defibrillator device includes means for storing data relating to the operation of the device following the application of a

defibrillation voltage to a patient, said control system may be responsive to a signal from said detector means to apply a compression algorithm to said stored data.

Accordingly the illustrated embodiment provides an improved automated external defibrillator (AED), which changes its operational state when touched or handled on a sensory section or sections of the casing. As illustrated this section comprises a handle area in the casing. However the section could be positioned anywhere about the device or alternatively multiple sensory sections could be located about the AED casing or the entire AED casing itself could form the sensory section.

The sensory section may consist of an electrical, mechanical, electromagnetic, thermal or otherwise sensor capable of detecting the presence of an object, such as an operator's hand either passively or actively. As illustrated the object must be touching the sensor section in order to be detected, however in alternative embodiments the object could be within a certain proximity of the casing in order to be detected.

Upon detection the defibrillator changes its operational state appropriate for the rescue. In the preferred embodiment the defibrillator changes from a sleep mode to an active mode. In this embodiment this is followed by audio and visual commands instructing the operator to what further actions he should do in order to carry out a rescue.

In other embodiments the defibrillator might turn from an off state to an on state. In another embodiment, detection results in the defibrillators operational mode entering a self-test state whereby the defibrillator checks that it is

performing correctly, it may then enter an on state automatically or as a result of a continued detection. Thus it becomes possible to check the defibrillator status without entering an on state by the operator touching the sensor section of the device and letting go.

DESCRIPTION OF THE PREFERRED EMBODIMENT

Whilst the invention has been described above it extends to any inventive combination of the features set out above or in the following description.

The invention may be performed in various ways, and, by way of example only, an embodiment thereof will now be described by way of example only, reference being made to the accompanying drawings in which:-

Figure 1 is a schematic view of an embodiment of a defibrillator in accordance with this invention, and

Figure 2 is a block diagram illustrating the control system of the defibrillator of Figure 1.

Referring initially to Figure 1, a semi-automatic automated external defibrillator in accordance with the invention is illustrated. The defibrillator includes a plastic case 10 with a carrying handle 12 on the top portion. The plastic casing 10 contains the storage battery control circuitry and associated equipment for the defibrillator. Associated with the handle 12 of the defibrillator is a handle switch 14 which, in this embodiment, is a capacitance switch although it could be a micro-switch. The casing 10 includes a compartment 16 for the storage of electrode pads 18 and appropriate sensors 20 and 22 may be provided to detect opening of the electrode compartment 16 and/or removal of the electrodes. The defibrillator includes a visual display screen 24 and a

loudspeaker 26 from which audio or visual instructions may be issued. The casing also includes an 'activation' button 28 and, internally of the casing, respective attitude sensors 30 and 32 for detecting the attitude of the casing relative to orthogonal axes. Also associated with casing is a further touch-sensitive region 34.

In operation, the defibrillator is arranged such that it switches from an OFF state to an ON state as soon as an operator grabs the handle.

One example of a control system for the defibrillator of Figure 1 is shown in Figure 2.

The rescue mode operation of the defibrillator is initiated when an operator grabs the handle 14 on the top portion in order to carry or move the defibrillator 10. The switch 14 mounted within the handle casing detects the grabbing of the handle and effectively functions as an on/off switch. In response to this action, a power control circuit 36 activates a power generation circuit 38 and initiates a rescue mode operation of a processor 40. The processor 40 then begins a rescue mode operation by performing a self-test and then initiates the generation of an audible voice prompt via the loudspeaker 26 "Take to rescue site and remove electrode pads." Such audio prompting may be reinforced or replaced by visual elements e.g. on a display 24 without departing from the scope of the patent.

Once the processor 40 has performed the self-test and on the condition that the defibrillator is functioning correctly, the processor then repeats the audio prompt, "Take to rescue site and remove pads."

Assuming that the handle is still being used to carry the defibrillator, the audio prompting will continue to repeat at a predetermined rate unless removal of the electrodes 18 from the defibrillator casing 10 has been detected by sensor 22, or removal of the electrodes upon the patient;. If desired, at a defined time following the initial grasping of the handle 12 the audio prompting may become less frequent or cease altogether. This would prevent the battery from being unnecessarily depleted powering the defibrillator system and will also prevent the device becoming a audible nuisance if it were just being transported without any form of carry case or bag. Should the device be placed down and then picked up again, reactivating the handle, the process would start from the beginning.

Upon removing the electrodes 18 from the casing and/or upon removing the electrodes from their associated packaging, the processor 40 guides the operator through a sequence of actions required to enable the AED to achieve a stage capable of performing an ECG analysis and subsequent rescue shock if necessary. This typically involves placing the electrodes 18 upon the patients' chest, checking the airway, breathing and circulation of the patient and monitoring the impedance between the electrodes for future reference if a shock were to be required.

In another embodiment if the processor detects that the defibrillator has been activated and then deactivated, e.g. by the operator grabbing the handle and subsequently placing the unit down and releasing the handle, it may issue verbal instructions to guide the operator to attach a pair of defibrillator electrodes 18 not presently connected. Furthermore in another variation, the processor

may detect when the electrode pads are connected and when they are not automatically, and issue a suitable announcement such as e.g. "unit in travel mode" or "unit OK" as appropriate. In a third embodiment the defibrillator may guide the operator to touch a further "activation" or "continue rescue" button 28 in order for the rescue to proceed.

In a fourth embodiment the defibrillator may have further sensors to detect at which stage the rescue is currently at and determine its audible or visual prompts accordingly. Such sensors may be attitude sensors 30, 32 capable of detecting whether the device is vertical or horizontal, and whether the device has been mistakenly placed on the ground the wrong way round. These sensors may only activate when the handle activation button 14 is released, or alternatively may be active for a predetermined time relative to the activation of the handle button 14.

Naturally after the completion of a rescue the operator will activate the handle sensor 14 again when attempting to place the defibrillator back in storage or transport the unit with the patient to a nearby hospital facility.

This post-rescue activation will cause the processor 40 to collect and to provide post-rescue data. This way includes instructions as to how to download or transfer any rescue data that may be held in memory, or as to the state of the battery and whether a recharge or replace will be necessary, or instruct the operator to replace the electrodes 18 used during the rescue.

Furthermore, the defibrillator contains an output interface 44 to enable any stored data to be transferred to a remote or local data storage or processing facility either directly by electrical cable, infra-red communication or wireless

applications or via connection to a modem and subsequently to a communication network (for example across an internet or intranet connection). Such data may include collected data during a rescue such as ECG, impedance, respiration, defibrillation data and audio or visual data collected by a microphone or camera as well as data collected during the defibrillator 's lifetime (self test data, event history etc).

Traditionally such data will require a large amount of memory and transfer across a data connection can take anywhere up to an hour if the connection is not high speed or if the data connection has a large amount of data traffic at that time. As can be appreciated requiring such a large amount of time to study any urgent data is not acceptable.

To reduce this data transfer time post-rescue, gripping the handle 12 after use signals the defibrillator to compress the data stored in a memory 46 using a compression algorithm 48 prior to the transfer of data. Such a compression operation on such a large amount of data can take up to ten minutes or so. Hence such an essential operation is performed while the defibrillator is in transit to either a carry bag or being taken with the patient to a hospital and the unit is confirmed to not be in a rescue state (i.e the unit has been picked up). Should the handle switch 14 again be activated and new electrodes used to perform a second rescue, the compression can be halted and data relating to a new rescue stored in the available memory.

Following the release of the post-rescue handle activation the defibrillator 10 may perform an additional self test to ensure that no damage occurred during transit.

In summary therefore the described embodiment and the various possible modifications describe an automated or semi-automated defibrillator that automatically changes the operation mode, prior to any intended use, when an operator contacts a section or sections of the casing. In one embodiment operation mode of the defibrillator changes from a sleep mode to an on mode or alternatively the operation mode of the defibrillator changes from an off mode to an on mode.

Furthermore, the defibrillator can be designed to automatically change the operational mode when the operator has no contact with a section or sections of the casing for a predetermined amount of time. Thus the operational mode of the defibrillator may change from an on mode to a sleep mode or alternatively from an on mode to an off mode.

This automatic activation often decreases the time it takes the operator—particularly an inexperienced or anxious operator—to set up and use the AED to resuscitate a patient in cardiac arrest. Furthermore, the operational mode of the defibrillator can be configured to change to a self-test mode when an operator contacts a section or sections of the casing prior to or following any intended use of the defibrillator. Thus the tested functions could include the presence and interconnection of defibrillator electrodes, battery charge state and the operability of the high voltage circuit. Visual and audible indicators are used to alert an operator if faults are identified. A record of each self-test may be stored in memory, and can be subsequently retrieved through a communications port or transmitted to a communications device via a transmitter module.

1/2

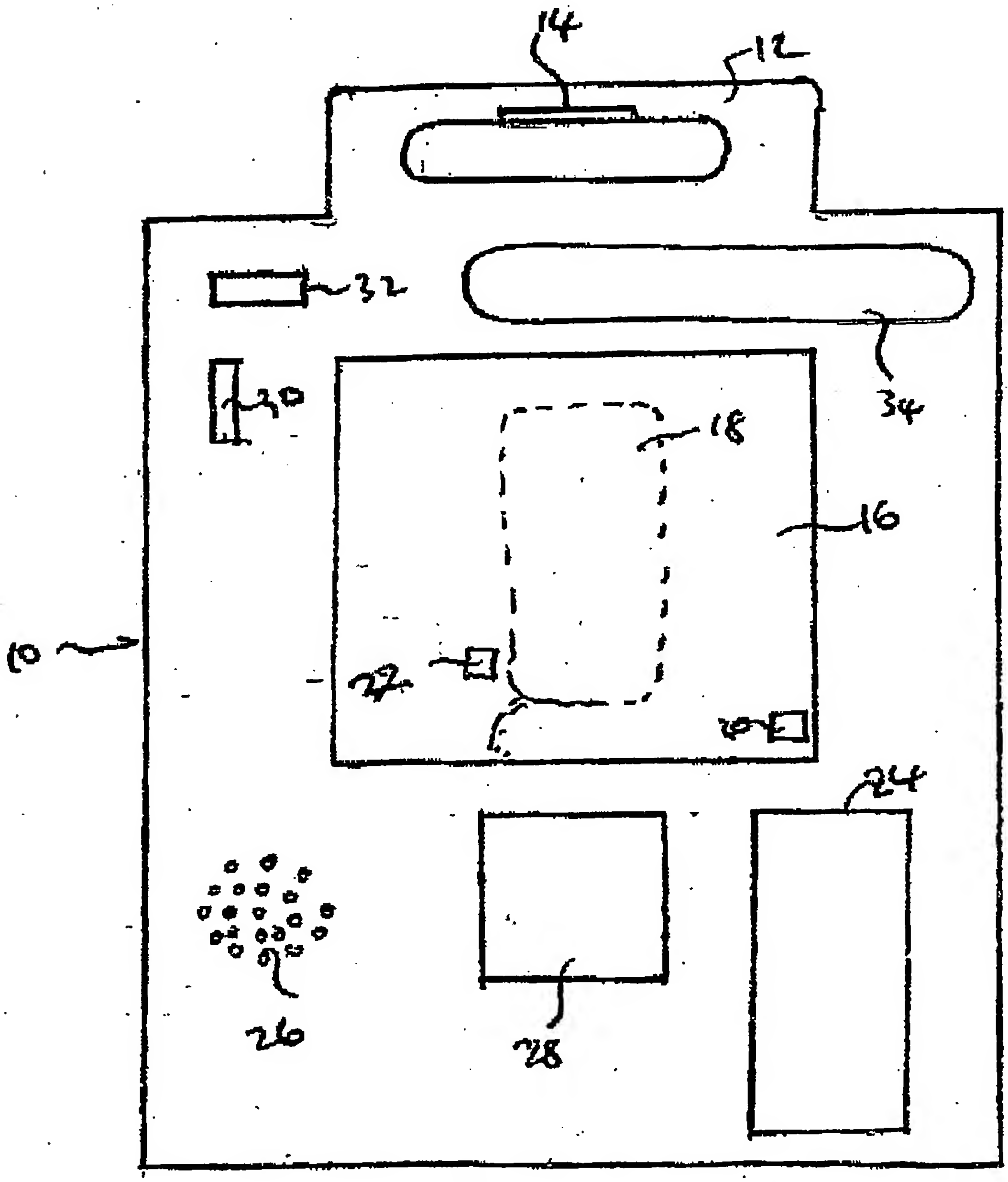
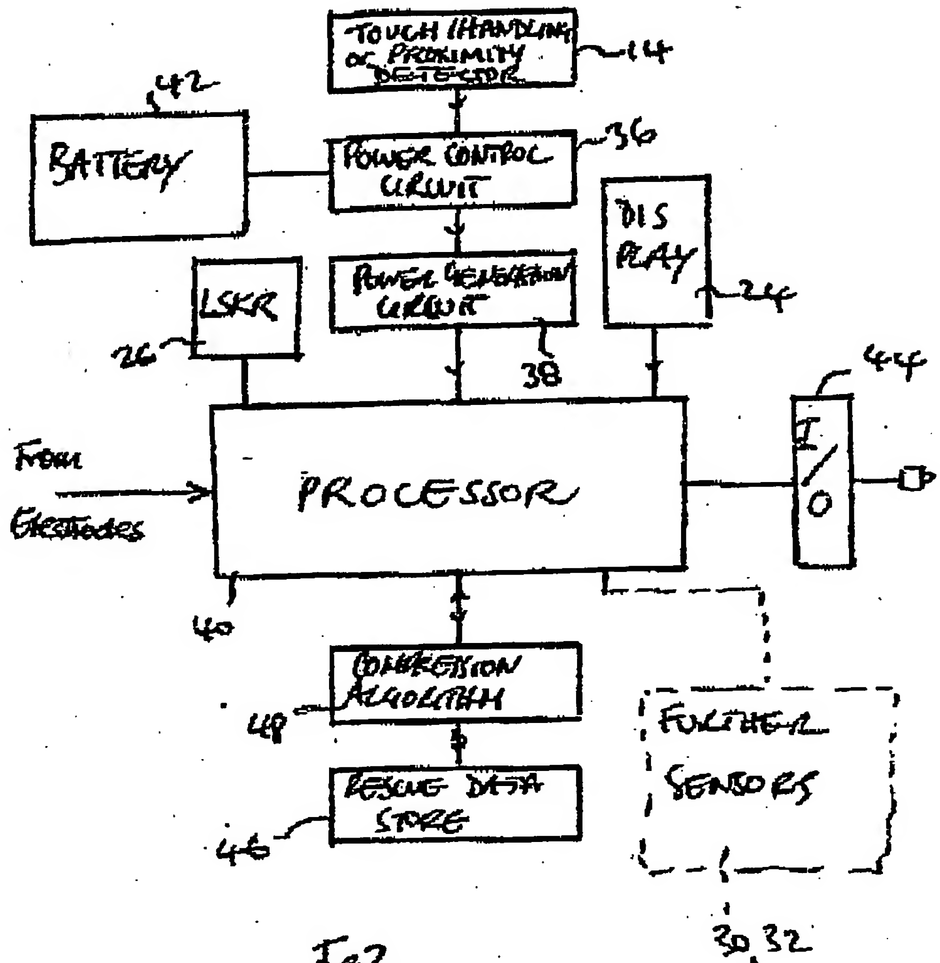


Fig1

2/2


TOUCH (HANDLING) OR PROXIMITY DETECTOR
14
42
BATTERY
POWER CONTROL CIRCUIT
36
DISPLAY
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POWER GENERATION CIRCUIT
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38
44
FROM ELECTRODES
PROCESSOR
I/O
40
CONVERSION ALGORITHM
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FURTHER SENSORS
RESCUE DATA STORE
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Fig2